UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	Oral Argument Requested

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' JOINT MOTION TO EXCLUDE OPINIONS OF JOHN QUICK

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

Pursuant to Federal Rules of Evidence 104, 702, and 703, Defendants' Executive Committee, on behalf of the undersigned Defendants, submit this Memorandum of Law in Support of Defendants' Joint Motion to Exclude Opinions of Plaintiffs' Expert John Quick.

INTRODUCTION

In support of class certification of their consumer economic loss claims, Plaintiffs have designated John Quick to offer expert opinions regarding the Manufacturer Defendants' compliance with the Federal Food, Drug, and Cosmetic Act ("FDCA") and current Good Manufacturing Practices ("cGMP") regulations in the manufacture of valsartan products. (*See* Quick Rep. ¶ 1.)[1] Mr. Quick's opinions constitute impermissible regulatory conclusions lacking any clear (let alone reliable) methodology and should therefore be excluded for multiple reasons.

First, Mr. Quick's opinions concerning adulteration, misbranding, and pharmaceutical manufacturer compliance with cGMPs are **impermissible legal and regulatory conclusions**. It is the role of the Court, not expert witnesses, to interpret federal regulatory law and instruct the jury as necessary.

Second, **Mr. Quick's regulatory opinions are unreliable**. Mr. Quick assumes that a drug manufacturer's single deviation from a cGMP renders any and

[1] The Expert Declaration of John Quick ("Quick Report") is attached to the accompanying Certification of Victoria Davis Lockard, Esq. as **Exhibit A.**

all manufactured products in the entire facility "adulterated" within the meaning of the FDCA, but he could not identify any support for this assumption and admitted that it does not align with his own prior experience working for a pharmaceutical manufacturing company. Mr. Quick also lacks support for his misbranding opinions, which rely solely on his own *ipse dixit*. And, in opining on cGMPs and Defendants' quality assurance systems, Mr. Quick ignored critical information related to, among other things, Standard Operating Procedures (SOPs), audits, Manufacturer Defendants' responses to FDA's observations, and nitrosamine levels for each Defendant's products.

Third, stripped of his legally impermissible and unreliable regulatory conclusions, all that remains of Mr. Quick's proposed testimony is **an impermissible factual narrative** based on a subset of documents. Because any lay juror can construe those documents without the assistance of an expert, this is not proper expert evidence and should be excluded as well.

For all of these reasons, discussed further below, Defendants respectfully submit that the Court should exclude Mr. Quick's opinions in their entirety.

BACKGROUND

Mr. Quick is a "Quality/Regulatory consultant" and former pharmaceutical executive at Baxter International. Inc., who has never worked for the FDA, or any other regulatory body, and has never consulted with the FDA. Mr. Quick seeks to

opine in the most conclusory fashion that each of the Manufacturer Defendants committed numerous quality assurance deviations and that those deviations "would have impacted each of the Manufacturer Defendants' valsartan products equally and in the same manner." (*See* Quick Rep. ¶ 191; Quick Dep., Vol. I, 106:7-12, 167:21-168:18.)[2] Mr. Quick also seeks to testify that the valsartan at issue was "adulterated" and "misbranded" within the meaning of the FDCA. (*Id.* ¶¶ 28-30.)

Specifically, Mr. Quick claims that the presence of "NDMA and/or NDEA" in active pharmaceutical ingredients results in "the product . . . being adulterated" (Quick Rep. ¶ 28), and that because "the presence of" the alleged impurities were not disclosed in "labeling, advertisements and/or patient booklets" the medications qualify as "misbranded" as well (*id.* ¶ 30). Mr. Quick does not limit his opinions to products that actually contained, or even might have contained, any impurities. Instead, he opines that any medication manufactured in the same facility as a drug that contains impurities qualifies as adulterated because the "facilities . . . did not have the appropriate cGMP quality assurance activities in place [that] would have prevented NDMA and/or NDEA from . . . being present in [any batches of] the product." (*Id.* ¶ 29; *see also* Quick Dep., Vol. I, 104:8-22) (claiming that the FDA defines "all products manufactured at [a] facility [as] adulterated if there is a "minor

[2] The transcript of the deposition of John Quick (Volumes I and II) is attached to the accompanying Certification of Victoria Davis Lockard, Esq. as **Exhibit B.**

observation about a single product line"). Mr. Quick further opines that "[b]ecause of the nature of th[e alleged cGMP deficiencies], they would have "impacted each of the Manufacturer Defendants' valsartan products equally and in the same manner." (Quick Rep. ¶ 191; *see id.* ¶ 102) ("[c]GMP [c]ompliance issues . . . would impact all the Defendants' [v]alsartan products").

ARGUMENT

The standards governing the admissibility of expert testimony at the class certification stage of litigation are set forth in Defendants' Memorandum of Law in Support of Defendants' Joint Motion to Exclude Opinions of Edward H. Kaplan, M.D., (*see* [Dkt. No. 2024-1] at 6-9), and are incorporated fully herein by reference. Mr. Quick's opinions fail under these standards.

I. MR. QUICK'S OPINIONS ARE IMPERMISSIBLE REGULATORY CONCLUSIONS.

As an expert witness, Mr. Quick may not offer his own opinions regarding regulatory law because the role of an expert is not to offer conclusions of law. *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006). Rather, that is the role of the Court and the finder of fact. Indeed, the "prohibition on experts testifying as to their own legal conclusions is so well established that it is often deemed a basic premise or assumption of evidence law—a kind of axiomatic principle." *Holman Enters. v. Fid. & Guar. Ins. Co.*, 563 F. Supp. 2d 467, 472 (D.N.J. June 30, 2008) (citing *United States v. Leo*, 941 F.2d 181, 196-97 (3d Cir.

1991)). "In fact, *every circuit* has explicitly held that experts may not invade the court's province by testifying on issues of law." *Id.* (emphasis added); *see also Casper v. SMG*, 389 F. Supp. 2d 618, 621 (D.N.J. 2005) (striking opinions of expert who applied case law and statutes to the documents and oral testimony in the case to answer legal questions such as whether the defendant was an "employer" within the meaning of a federal statute). "The district court *must* limit expert testimony so as to not allow experts to opine on 'what the law required' or 'testify as to the governing law.'" *Holman Enters.*, 563 F. Supp. 2d at 472 (quoting *Leo*, 941 F.2d at 196-97 (emphasis added)).

Applying these principles, courts around the country have routinely held that expert witnesses may not offer their own opinions on whether a pharmaceutical company complied with FDA regulations, including opinions about "adulteration" and "misbranding." *See, e.g.*, *Robinson v. Ethicon, Inc.*, No. H-20-03760, 2022 U.S. Dist. LEXIS 36441, at *20 (S.D. Tex. March 2, 2022) (regulatory expert prohibited from offering opinions that product was misbranded or adulterated, as these are impermissible legal conclusions); *In re Tylenol (Acetaminophen) Mktg., Sales Practices, & Prods. Liab. Litig.*, MDL No. 2436; Case No. 2:12-cv-07263, 2016 U.S. Dist. LEXIS 98858, at *8–9 (E.D. Pa. July 27, 2016) (excluding an expert opinion as to whether a drug met a certain standard pursuant to FDA regulations, as such "would require a legal interpretation" of that standard); *Tsao v. Ferring*

Pharms., Inc., No. 4:16-cv-01724, 2018 WL 3649714, at *11 (S.D. Tex. Apr. 19, 2018) (opinion by regulatory expert that drug was "misbranded" was "inadmissible legal conclusion[]."); *Stanley v. Novartis Pharms. Corp*., No. 11-03191, 2014 U.S. Dist. LEXIS 198861, at *10 (C.D. Cal. May 6, 2014) (precluding an expert from "offer[ing] legal conclusions, including whether Defendant was in regulatory compliance with the FDCA"); *In re: Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 557 (S.D.N.Y. 2004) (holding that opinions regarding "the duties of pharmaceutical companies are not appropriate expert testimony because they embrace ultimate questions of law outside the province of an expert").

Here, Mr. Quick's opinions concerning Defendants' regulatory compliance, specifically whether the at-issue valsartan was "adulterated" or "misbranded," and whether the Manufacturer Defendants complied with cGMPs, should be excluded because Mr. Quick does nothing more than regurgitate federal statutes, regulations, and information obtained from the FDA's website to draw impermissible (and flawed) legal conclusions. (*See* Quick Report ¶¶ 21, 22, 25, 31, 32.) Mr. Quick makes sweeping legal conclusions about "adulteration," "misbranding," and adherence to cGMPs, but these are complex, statutorily-defined regulatory determinations solely within the province of the FDA and Department of Justice. *See, e.g.*¸ *In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales* Practices, 701 F. Supp. 2d 356, 369 (E.D.N.Y. March 30, 2010) ("The FDCA's primary focus

is ensuring that drugs are safe, effective, and not misbranded, which the FDA ensures by enforcing the regulations."); 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.").

After quoting the statutory definition of "adulterated" from 21 U.S.C. § 351(a) (*see* Quick Report ¶ 22) and of "misbranded" from 21 U.S.C. § 352(a) (*id.* ¶ 27), Mr. Quick then offers his own personal conclusions (purportedly based on those FDCA definitions) about whether Defendants complied with regulatory requirements. According to Mr. Quick, "[t]he fact that the Manufacturer Defendants' valsartan products were manufactured in facilities that did not have the appropriate cGMP quality assurance activities in place, . . . results in the Defendants' valsartan products being adulterated," and "[b]ecause the presence of NDMA and/or NDEA was not revealed in the labeling, advertisements, and/or patient booklets given to consumers at the time of dispensing, this also resulted in the Defendants' [v]alsartan products being misbranded." (Quick Rep. ¶¶ 29-30; *see also id.* ¶ 28 ("The fact that NDMA and/or NDEA (and other contaminants) were present in the API and ultimately in the finished drug product results in the product . . . being adulterated.").) Similarly, after providing a lengthy (12-page) recitation of the FDA's cGMP regulations and guidances (Quick Rep. ¶¶ 31-100), Mr. Quick provides his own personal conclusions about whether Defendants were complying with FDA cGMPs at the times the

valsartan drugs were sold to the putative class members (Quick Rep. ¶¶ 101-186.) Mr. Quick's opinions are impermissible regulatory conclusions and are not the subject of appropriate expert testimony.

At points in his deposition, Mr. Quick sought to directly characterize his conclusions as FDA's conclusions:

> Q: Is it your opinion that a single minor observation about a single product line . . . represents the FDA's determination that all products manufactured at that facility are adulterated?
>
> . . .
>
> A: That's not what I've stated. What I'm stating is what FDA has stated. If a company is not complying with cGMP regulations, any drug it makes is considered adulterated under the law. **That's what the FDA states. That's not what John Quick states. That's what the FDA states.**

(Quick Dep., Vol I., 104:8-22 (emphasis added); *see also id.* at 108:22-109:13 ("I'm just telling you what the FDA says about cGMP violations. . . . I'm just telling you what the FDA does say about cGMP violations relative to adulteration.").)

Even if this testimony were accurate—which it is not—it would only serve to underline that Mr. Quick seeks to offer legal opinions. The content of federal regulations is squarely within the province of the Court, and an expert may not "usurp the District Court's pivotal role in explaining the law to the jury." *In re Tylenol*, 2016 U.S. Dist. LEXIS 98858, at *7-8. In any event, Mr. Quick himself ultimately conceded that he does not, and cannot, speak for the FDA. (Quick Dep.,

Vol. I., 132:18 ("Of course I'm not here to speak for FDA.").)

Put simply, Mr. Quick's opinions on cGMPs, adulteration, and misbranding fall squarely within the well-recognized prohibition against experts offering legal/regulatory conclusions and, for this reason alone, should be excluded.

II. MR. QUICK'S OPINIONS ARE UNRELIABLE.

Mr. Quick's regulatory opinions are separately inadmissible because they are not reliable. In assessing the reliability of an expert's methodology, courts are to consider "all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinions, and the link between the facts and the conclusion." *In re Johnson & Johnson Derivative Litig.*, 900 F. Supp. 2d 467, 493, (D.N.J. Oct. 26, 2012) (quoting *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 155 (3d Cir. 1999)). "An expert's opinion must be based 'on scientific, technical or other specialized knowledge and not on subjective belief or unsupported speculation." *In re Diet Drugs Prods. Liab. Litig.*, MDL Dkt. No. 1203, 2000 U.S. Dist. LEXIS 9661, at *12 (E.D. Pa. June 28, 2000) (internal citations omitted).

A. Mr. Quick's Opinions Are Based on Unsupported and Erroneous Assumptions.

Mr. Quick's regulatory conclusions are rooted in the incorrect belief that a manufacturer's non-compliance with *any* cGMP, regardless of the type or severity, renders *all* product produced at that manufacturer's facility adulterated within the meaning of the FDCA. Thus, in his opinion, a cGMP violation related to one drug

on one particular manufacturing line at a facility would render *other* drugs manufactured in an entirely different room at that facility "adulterated."[3] This opinion is based solely on Mr. Quick's "*ipse dixit*," and should therefore be excluded.

"[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence [that] is connected to existing data only by the *ipse dixit* of the expert." *General Elec. Co. v. Joiner*, 522 U.S. 136, 147 (1997)). Although an expert can rely on factual assumptions in reaching his opinions, those factual assumptions must be supported. "[T]he expert must have good grounds for his o[r] her belief," and the opinion cannot be based "on subjective belief or unsupported speculation." *Calhoun v. Yamaha Motor* Corp*., U.S.A.*, 350 F.3d 316, 321 (3d Cir. 2003) (internal citations omitted); *see Holman Enters.*, 563 F. Supp. 2d at 471 ("An expert opinion is not admissible if the court concludes that an opinion based upon particular facts cannot be grounded upon those facts.") (citing *Fedorczyk v. Caribbean Cruise Lines, Ltd.*, 82 F.3d 69, 75 (3d Cir. 1996)); *In re Hum. Tissue*

[3] As noted above, whether a drug is "adulterated" is a statutorily-defined regulatory determination, and the FDA alone has the authority to make that determination. *See* 21 U.S.C. § 351(a); *see also, e.g.*, *Robinson*, 2022 U.S. Dist. LEXIS 36441, at *6 (holding that expert "cannot take the final step of opining that the product was 'misbranded' or 'adulterated,' as these are impermissible legal conclusions").

Prods. Liab. Litig., 582 F. Supp. 2d 644, 679 (D.N.J. 2008) (excluding opinion that "ha[d] no basis in any specific medical literature and [wa]s merely based upon [expert's] belief").

Mr. Quick has no basis at all, let alone "good grounds," for his theory. Mr. Quick opines that "FDA's official position regarding cGMPs is that if a company is not complying with cGMP regulations, any drug it makes is considered 'adulterated' under the law." (*See* Quick Report ¶ 32.) But Mr. Quick's broad and incorrect opinion about the FDA's "official position" does not come from an official FDA statute, regulation, or guidance document. Rather, he bases his regulatory conclusion on one sentence plucked from an FDA information webpage about cGMPs: "If a company is not complying with CGMP regulations, any drug it makes is considered 'adulterated' under the law."[4] This *single sentence*, however, does *not* establish that the FDA's official position is such a sweeping one that non-compliance with *any* cGMP, regardless of the type or severity, renders *all* product produced at that manufacturer's facility adulterated within the meaning of the FDCA. Notably, the FDA webpage follows the quotation Mr. Quick highlights with: "This kind of adulteration means that the drug was not manufactured under conditions that comply with CGMP. It does not mean that there is necessarily something wrong with the

[4] *See Facts About the Current Good Manufacturing Practices (CGMPs)*, https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps (last visited April 26, 2022).

drug."[5] Moreover, when pressed during his deposition, Mr. Quick could not point to any other authority to support his speculative statement that any and all product produced anywhere in a facility becomes adulterated as the result of any single cGMP violation. (*See* Quick Dep. Vol. I, 96:16-97:15).

Mr. Quick's own past experience in the pharmaceutical industry as a quality executive at Baxter demonstrates that his current opinion that a cGMP violation renders all product produced in a facility adulterated was made for this litigation. *See In re Fosamax Prods. Liab. Litig.*, No. 1:06-md-1789, 2009 WL 2878439, at *5 (S.D.N.Y. Sept. 9, 2009) (excluding opinion contrary to the one offered in expert's professional work; reversal of opinion "raises a question as to whether it was made independent of litigation concerns"). Although Mr. Quick now opines that a single deviation from a cGMP renders any and all manufactured product in a facility adulterated, he conceded that when Baxter received FDA warning letters under his leadership, he never required the company to recall or to stop distribution of all product manufactured in the subject facility: "Q: So, again, my question was, you didn't initiate a recall, and you didn't initiate a distribution hold, yet you considered all of the product manufactured at that facility to be adulterated? A: Under the context of this, yes." (Quick Dep, Vol. I, 151:18-23.)

[5] *Id.*

As a practical matter, it is clear to see why. It could not conceivably be that any deviation from a cGMP renders all product manufactured at a facility adulterated within the meaning of the FDCA. If all product manufactured at a facility were "adulterated" because of one cGMP deviation—regardless of the severity—a staggering proportion of all drug product currently marketed and sold in the United States, both branded and generic, would be considered "adulterated." A review of the FDA's Dashboard data detailing the number of quality assurance inspections in any given year shows the impracticality of Mr. Quick's personal interpretation. There were over 12,000 drug quality assurance inspections from 2012-2018, with over 6,700 categorized as VAI (voluntary action indicated) and over 1,000 categorized as OAI (official action indicated). *See* FDA Inspection Dashboard, *available at* https://datadashboard.fda.gov/ora/cd/inspections.htm (last visited April 26, 2022). These inspections resulted in over 17,000 citations and involved *over 4,300* different manufacturers. *Id.* If Mr. Quick's overbroad, facility-wide, retrospective position were correct, essentially every drug on the market would be "adulterated." For this reason, too, his opinions should be excluded.[6]

[6] For these reasons, Mr. Quick's opinions are also excludable because his flawed and unworkable interpretation of FDA regulations would serve only to confuse or mislead, and not *help* the trier of fact. *See In re Paoli R. Yard PCB Litig.*, 1992 U.S. Dist. LEXIS 18430, at *44-45 (E.D. Pa. Oct. 21, 1992) ("An opinion based on false assumptions is unhelpful in aiding the jury in its search for the truth, and is likely to mislead and confuse.").

B. Mr. Quick Has Absolutely No Basis for His Legal Conclusion That the Valsartan At Issue Was Misbranded.

Mr. Quick's legal conclusion that valsartan was misbranded should be excluded as well, because it was proffered without any support. *See Joiner*, 522 U.S. at 147 (explaining that court should not accept opinions backed "only by the *ipse dixit* of the expert"). Mr. Quick opines that "[b]ecause the presence of NDMA and/or NDEA was not revealed in the labeling, advertisements and/or patient booklets given to consumers at the time of dispensing, this . . . resulted in the Defendants' valsartan products being misbranded." (Quick Rep. ¶ 30.) This is pure *ipse dixit*. Mr. Quick did not employ any methodology in reaching this conclusion. In fact, he lacks even basic knowledge of the FDA's labeling requirements:

> Q: Now, labeling of allowable impurities or disclosing impurities in any amount on a marketed drug product label is not something that's required in an ANDA. Correct?
>
> . . .
>
> A: ***I'm not sure***. I haven't looked at what actually is required on the labeling other than – no.
>
> Q: Okay. So do you know one way or the other whether labeling of product potency within allowable limits is required by FDA?
>
> . . .
>
> A: Well, the potency would be on the labeling.
>
> Q: And that is required by FDA. Right?

> A: Well, again, that's not something I'm opining on but, yes, I would assume so.
>
> Q: Okay. At any time did FDA require any manufacturer to change it – its approved labeling to declare that NDMA or NDEA be listed as impurities on their [ ] valsartan product labels?
>
> A: ***I don't know.***

(Quick Dep., Vol. I, 143:21-145:5) (Emphasis added).

This "methodology" is worse than flimsy—it is non-existent. Mr. Quick's *ipse dixit* misbranding opinion is not only an impermissible regulatory conclusion, but also demonstrates no indicia of reliability and therefore should be excluded.

C. In Opining on Defendants' cGMPs and Quality Assurance Systems, Mr. Quick Admits He Had No System for Selecting the Documents He Reviewed and Neglected to Review Critical Documents.

All of Mr. Quick's opinions regarding the Manufacturing Defendants' cGMP and quality assurance systems are also unreliable because he did not perform a rigorous and methodical analysis of the available data and therefore ignored a host of critical documents and information. The touchstone for a *Daubert* analysis is "that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999). Thus, an expert opinion is inadmissible if the person offering it "has not considered all of the relevant facts." *Concord Board*

Corp. v. Brunswick Corp., 207 F.3d 1039, 1056 (8th Cir. 2000).

Mr. Quick's opinion fails to satisfy this standard. By his own admission, Mr. Quick merely selected example documents to review, without "necessarily hav[ing] any system to pick these particular examples." (Quick Dep., Vol. II, 11:6-9; *see* Quick Dep., Vol. I, 168:12-18 ("no specific determination" to decide "which examples [he] would review").)

Mr. Quick's lack of any systematic methodology led him to lob blanket criticism of Defendants' quality assurance systems, while failing to review a host of critical documents concerning them. Among other things, he did not review Defendants' standard operating procedures, or even determine whether they existed, despite acknowledging that such review was necessary to determine their adequacy. (*See* Quick Dep., Vol. I, 160:3-161:12.) He did not review the United States Pharmacopeia's monograph to determine approved testing standards for valsartan impurities. (*Id.* at 83:13-23.) He also failed to assess the quality departments of certain manufacturers (*see id.* at 239:4-16), or review audits (*see id.* 186:7-22), or consider the Manufacturer Defendants' responses to observations by the FDA (*id.* at 248:18-25; Quick Dep., Vol. II, 112:11-16). Perhaps most strikingly of all, he did not even "review [NDMA/NDEA] levels for each defendants' products," despite acknowledging that the information is "relevant, because that's the basis for many

of the issues that the FDA had." (Quick Dep., Vol. I, 76:17-77:4.)[7] These shortcomings render Mr. Quick's ultimate conclusions, including that the cGMP violations he purported to identify can be presumed to be common throughout the proposed class, unreliable, and thus inadmissible under Rule 702.[8]

III. MR. QUICK'S REMAINING OPINIONS CONSTITUTE AN INADMISSIBLE FACTUAL NARRATIVE.

Mr. Quick's testimony is also inadmissible to the extent he simply recites selected facts concerning alleged cGMP violations and the manufacturers' quality assurance systems. A factual narrative is not a proper stand-alone opinion, because "[t]he jury can consider the facts directly and draw their own conclusions." *Miller v. Stryker Instruments*, No. CV 09-813-PHX-SRB, 2012 U.S. Dist. LEXIS 70314, at *36 (D. Ariz. March 29, 2012); *see, e.g.*, *In re Fosamax Prods. Liab. Litig.*, 645 F.

[7] Further, although he purportedly relied on the testimony of certain corporate witnesses in reaching his opinions (*see, e.g.*, Quick Report ¶¶ 110, 161), Mr. Quick admitted that he only "skimmed through" the deposition testimony of the manufacturers' corporate witnesses, only identified which depositions to skim through based on Plaintiffs' counsels' recommendations, and did not attempt to determine whether any portions of the testimony he had been recommended to read were contradicted by other portions of testimony. (*See* Quick Dep., Vol. II, 19:14 - 21:7).

[8] For example, although Mr. Quick cited Teva for failing to have certain quality systems in place, Timothy Anderson, MS, MBA, Teva's class certification expert, demonstrated that Teva had cGMP-compliant policies in place with respect to each and every one of these areas, which Mr. Quick failed to consider. *See generally*, Expert Report of Timothy Anderson, MS, MBA, attached to the accompanying Certification of Victoria Davis Lockard, Esq. as **Exhibit C**.

Supp. 2d 164, 192 (S.D.N.Y. 2009) ("[The expert's] report presents a narrative of select regulatory events through the summary or selective quotation from internal Merck documents, regulatory filings, and the deposition testimony of Merck employees . . . . [T]o the extent such evidence is admissible, it should be presented to the jury directly."); *In re Rezulin*, 309 F. Supp. 2d at 551 (rejecting portion of expert report presenting history of Rezulin for no purpose but to "provid[e] an historical commentary of what happened"); *Highland Capital Mgmt., L.P. v. Schneider*, 379 F. Supp. 2d 461, 469 (S.D.N.Y. 2005) ("An expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based upon record evidence."); *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1346 (S.D. Fla. April 27, 2010) ("[W]hile the report cites to some FDA regulations, it mostly consists of a factual narrative of Trasylol's regulatory history and summaries of Bayer's internal documents. [The expert] does not analyze the facts; she . . . regurgitates them and reaches conclusory opinions that are purportedly based on these facts.").

Stripped of the improper regulatory law conclusions, Mr. Quick's report consists of a (one-sided) historical narrative constructed primarily from cherry-picked quotations or summaries of company documents, supplemented with snippets of deposition transcripts. To the extent such evidence is relevant and admissible, it can be presented to—and understood by—the jury directly without the imprimatur

of an expert.

CONCLUSION

For foregoing reasons, Defendants respectfully request that the Court exclude the opinions of Plaintiffs' expert John Quick.

Dated: May 3, 2022

Respectfully Submitted:

By: */s/ Victoria Davis Lockard*

GREENBERG TRAURIG, LLP
Lori G. Cohen
Victoria Davis Lockard
Steven M. Harkins
Terminus 200
3333 Piedmont Road, N.E.,
Suite 2500
Atlanta, Georgia 30305
Tel. (678) 553-2100
Fax. (678) 553-2386
CohenL@gtlaw.com
LockardV@gtlaw.com
HarkinsS@gtlaw.com

Counsel for Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis Pharma, Inc., and Actavis LLC

SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP
Jessica D. Miller, *Liaison Counsel for Manufacturer Defendants*
Nina R. Rose
1440 New York Ave., N.W.
Washington, D.C. 20005
Tel.: (202) 371-7000
Fax: (202) 661-0525
jessica.miller@skadden.com
nina.rose@skadden.com

Counsel for Zhejiang Huahai Pharmaceutical Co, Ltd., Huahai U.S., Inc., Prinston Pharmaceutical Inc. and Solco Healthcare US, LLC

PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP
Clem C. Trischler
Jason M. Reefer
Frank H. Stoy
38th Floor, One Oxford Centre
Pittsburgh, Pennsylvania 15219
Tel: (412) 263-2000
Fax: (412) 263-2001
cct@pietragallo.com
jmr@pietragallo.com
fhs@pietragallo.com

Counsel for Mylan Laboratories, Ltd. and Mylan Pharmaceuticals, Inc.

KIRKLAND & ELLIS LLP
Devora W. Allon
Alexia R. Brancato
601 Lexington Avenue
New York, New York 10022
Tel: (212) 446-5967
Fax: (212) 446-6460
devora.allon@kirkland.com
alexia.brancato@kirkland.com

Attorneys for Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc.

MORGAN, LEWIS & BOCKIUS LLP
John P. Lavelle, Jr.
1701 Market Street
Philadelphia, Pennsylvania 19103
Tel: (215) 963-5000
Fax: (215) 963-5001
john.lavelle@morganlewis.com

John K. Gisleson
One Oxford Centre, Thirty-Second Floor
Pittsburgh, Pennsylvania 15219
Tel: (412) 560-3300
Fax: (412) 560-7001
john.gisleson@morganlewis.com

Attorneys for Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC

LEWIS BRISBOIS BISGAARD & SMITH LLP
Walter H. Swayze, III
Andrew F. Albero
550 E. Swedesford Road, Suite 270
Wayne, Pennsylvania 19087
Tel: (215) 977-4100
Fax: (215) 977-4101
pete.swayze@lewisbrisbois.com
andrew.albero@lewisbrisbois.com

Attorneys for Camber Pharmaceuticals, Inc. and The Kroger Co.

HILL WALLACK LLP
Eric I. Abraham
William P. Murtha
21 Roszel Road
P.O. Box 5226
Princeton, New Jersey 08543-5226
Tel: (609) 734-6358
Fax: (609) 452-1888
eabraham@hillwallack.com
wmurtha@hillwallack.com

Attorneys for Hetero Drugs, Ltd. and Hetero Labs Ltd.

HARDIN KUNDLA MCKEON & POLETTO
Janet L. Poletto, Esq.
Robert E. Blanton, Jr., Esq.
673 Morris Ave.
Springfield, New Jersey 07081
Tel: (973) 912-5222
Fax: (973) 912-9212
jpoletto@hkmpp.com
rblanton@hkmpp.com

Attorneys for Hetero USA Inc.

BARNES & THORNBURG LLP
Sarah E. Johnston, *Liaison Counsel for Retailer Defendants*
Kristen L. Richer
2029 Century Park East, Suite 300
Los Angeles, CA 90067
Tel: (310) 284-3798
Fax: (310) 284-3894
sarah.johnston@btlaw.com
Kristen.Richer@btlaw.com

Kara M. Kapke
11 S Meridian St.
Indianapolis, Indiana 46204
Tel: (317) 236-1313
Fax (317) 231-7433
kara.kapke@btlaw.com

Attorneys for CVS Pharmacy, Inc. (incorrectly named as CVS Health Corporation), Rite Aid Corporation, Walgreen Co. (incorrectly named as Walgreens Co.), and Walmart Inc. (incorrectly named as Walmart Stores, Inc.)

HUSCH BLACKWELL LLP
Matt Knepper
James Spung
190 Carondelet Plaza
Suite 600
St. Louis, Missouri 63105
Tel: (314) 480-1500
Fax: (314) 480-1505
matt.knepper@huschblackwell.com
james.spung@huschblackwell.com

Attorneys for Express Scripts, Inc.

DORSEY & WHITNEY LLP
Roxanna Gonzalez
51 West 52nd Street
New York, New York 10019
Tel: (212) 415-9357
Fax: (212) 953-7201
gonzalez.roxanna@dorsey.com

Attorneys for Optum, Inc. and Optum Rx

BUCHANAN INGERSOLL & ROONEY PC
Jonathan D. Janow
Jason R. Parish
1700 K Street NW
Suite 300
Washington, DC 20006
Tel: (202) 452-7940
Fax: (202) 452-7989
jonathan.janow@bipc.com
jason.parish@bipc.com

Attorneys for Albertson's LLC

ULMER & BERNE LLP
Jeffrey D. Geoppinger
Liaison Counsel for Wholesalers
312 Walnut Street, Suite 1400
Cincinnati, OH 45202-2409
Tel: (513) 698-5038
Fax: (513) 698-5039
Email: jgeoppinger@ulmer.com

Counsel for AmerisourceBergen Corporation

CROWELL & MORING
Andrew D. Kaplan
Daniel T. Campbell
Marie S. Dennis
1001 Pennsylvania Avenue, NW
Washington, DC 20004
Tel: (202) 624-1000
Fax: (202) 628-5116
Email: akaplan@crowell.com
Email: dcampbell@crowell.com
Email: mdennis@crowell.com

Counsel for Cardinal Health, Inc.

NORTON ROSE FULBRIGHT US LLP
D'Lesli M. Davis
Ellie K. Norris
2200 Ross Avenue, Suite 3600
Dallas, TX 75201-7932
Tel: (214) 855-8221
Fax: (214) 855-8200
dlesli.davis@nortonrosefulbright.com
ellie.norris@nortonrosefulbrigth.com

Counsel for McKesson Corporation

CERTIFICATE OF SERVICE

I, Kate Wittlake, an attorney, hereby certify that on May 3, 2022, I caused a copy of the foregoing document to be served on all counsel of record via CM/ECF.

/s/ Kate Wittlake
Kate Wittlake
Greenberg Traurig, LLP